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10/699,562

10/31/2003

Tao Jiang

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/699,562

Applicant(s)

JIANG ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/28/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32, 37 and 45-56 is/are pending in the application.
- 4a) Of the above claim(s) 49-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32, 37, 45-48 and 54-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 2/28/07 wherein claims 1, 11, 46, and 47 were amended and claims 33-36 and 38-44 were canceled.

Note: Claims 1-32, 37, and 45-56 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments and/or amendment filed 2/28/07 to the rejection of the claims made by the Examiner under 35 USC 112, first and second, paragraph and double patenting rejections have been fully considered and deemed persuasive-in-part for the reasons set forth below.

Statutory Double Patenting Rejections

The statutory double patenting rejections are WITHDRAWN because Applicant has amended the claims to overcome the rejections. However, double patenting rejection are now being made under obviousness-type double patenting because the amended claims are now obvious over copending application numbers 11/133,804 and 11/437,095.

112 First Paragraph Rejection (Prevention Claim)

The rejection of claims 1-32, 37, 45-48, and 54-56 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement is MAINTAINED for reasons of record in the office action mailed 11/30/06 and those set forth below.

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In summary, Applicant asserts that the claims generally recite the 'prevention' of cellular uptake of portion B which serves as a veto to prevent the uptake of B with linked to A. However, based on the Examiner's rejection involving the lack of enablement of disease prevention is not applicable to the instant invention. Applicant asserts that the specification provides ample evidence that an acidic amino acid containing portion A is able to prevent the uptake of a linked basic portion, B. Applicant cited Examples 3-6 and Figures 7-11 of the specification for support of the used of the term 'prevent'. Thus, Applicant asserts that the claims are enabled and the rejection should be withdrawn.

First, it is noted that none of the peptides of Examples 3-6 and Figures 7-11 include SEQ. ID No. 1 as set forth in the amended claims. Example 3, for example, discloses that peptides showing the ability of oligoglutamates to veto oligoarginine mediated cellular uptake include SEQ ID Nos. 5-13. Also, note that Example 3 discloses peptides having acidic portions, specifically, peptides having fluorescent cargo moieties connected to basic portions having multiple arginine residues. This is not true for the amended claims, for example, which are directed to PLGLAG containing peptides. In addition, it is disclosed that the peptides are also linked by cleavable linkers to an acidic portion having multiple glutamate residues. Thus, Applicant has shown that cellular uptake is prevented at very specific conditions. Hence, since independent claims 1, 11, and 46 is not limited to such conditions. Thus, Applicant is not enabled for the prevention of cellular uptake of all peptides.

112 Second Paragraph Rejections

The 112 second paragraph rejections are WITHDRAWN.

WITHDRAWN CLAIMS

3. Claims 49-53 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

NEW GROUNDS OF REJECTIONS

Obviousness-Type Double Patenting Rejections

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 11 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, and 21 of copending Application No. 11/133,804. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to molecules comprising PLGLAG peptide sequences. The claims differ in that the instant invention discloses that PLGLAG is present in the independent claim whereas application number discloses that PLGLAG is the peptide of interest in one of the dependent claims. Thus, a skilled practitioner in the art would recognize that 11/133,804 encompasses the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claim 11 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, and 21 of copending Application No. 11/437,095. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to

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molecules comprising PLGLAG peptide sequences. The claims differ in that the instant invention discloses that PLGLAG is present in the independent claim whereas application number discloses that PLGLAG is the peptide of interest in one of the dependent claims. Thus, a skilled practitioner in the art would recognize that 11/437,095 encompasses the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 Second Paragraph Rejection

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54 and 55: The claims as written are ambiguous because they depend upon canceled claim 39.

COMMENTS/NOTES

9. It is once again noted that no prior art has been cited against the instant invention. However, Applicant MUST address and overcome the double patenting and 112 rejections above. In particular, the claims are distinguished over the prior art of

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record because the prior art neither anticipates nor renders obvious molecular products as set forth in independent claims 1, 11, and 46 comprising SEQ ID No. 1.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
Art Unit 1618

June 8, 2007